UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,270	09/24/2003	Peter A. Altman	212/511	3869

23371 7590 09/26/2008

CROCKETT & CROCKETT, P.C.
26020 ACERO
SUITE 200
MISSION VIEJO, CA 92691

EXAMINER	
CHENG, JACQUELINE	
ART UNIT	PAPER NUMBER
3768	

MAIL DATE	DELIVERY MODE
09/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/671,270	ALTMAN ET AL.	
	Examiner	Art Unit	
	JACQUELINE CHENG	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed February 25, 2008 have been fully considered but they are not persuasive. The examiner believes the rejection of Barry (US 5,439,446) in view of Stevens (US 6,152,141) still stands. Barry discloses most of what is claimed except for explicitly disclosing using the stent and agent in a coronary blood vessel. However as Barry does not limit the use of the stent in a particular vessel, it would be obvious to use the stent in any vessel that it is well known to apply a stent to such as in a coronary blood vessel as disclosed in Stevens. Stevens also discloses multiple methods of injecting a therapeutic agents, and teaches that these methods are interchangeable. Some of the methods that Stevens teaches are by injecting the agent through a port and by injecting the agent with needles. It would therefore be obvious to use the injection methods of Stevens in Barry as they are all functional equivalents and any of the methods can be used as taught by Stevens. One of the needle injection methods of Stevens comprises jet infusing the agent through needles protruding from a balloon, which as can be seen in fig. 11b and in fig. 12, is and can be, peri-adventitially (col. 8 line 66-col. 9 line 35). Another method of applying the agent is by piercing the artery wall and injecting the agent directly into the myocardium from the endocardium (fig. 10b, col. 8 line 27-65).

2. As to the combination of Mixon (US 6,090,728) and Rossi (US 6,379,931). It is well known in the art that anti-angiogenic agents are used as agents for treating restenosis (see US 6,511,477, US 5,843,089, US 5,886,026). It would therefore be obvious to one skilled in the art at the time of the invention to use any agent, such as an anti-angiogenic agent, well known for

treating restenosis such as the anti-angeiogenic agent of Mixon or the liposome containing a ribozyme of Rossi as the agent in Barry.

3. As to the rejection of claim 41 under Stevens in view of Kunz (US 5,981,568), Kunz teaches that it is obvious to provide a kit with instructions of how to use the kit in the art of applying therapeutic agents. Therefore it would be obvious that to apply the method of Stevens, one would have a kit and an instruction set of how to operate the method of Stevens which includes positioning a catheter and delivering the dose.

4. Therefore the rejections under Barry in view of Stevens, Barry in view of Stevens in view of Mixon, Barry in view of Stevens in view of Rossi, and Stevens in view of Kunz still stand. The office action dated September 24, 2007 is repeated below for your convenience.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. **Claims 1-6, 11-16, 21-26, and 31-36** are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry (US 5,439,446) further in view of Stevens (US 6,152,141). Barry discloses an apparatus for treating irregularities in a vessel of a patient such as a stenosis (col. 4 line 27-32). The apparatus comprises of a stent and administration of therapeutic agents to reduce the risk of restenosis (col. 3 line 38-57). Stents are used in many applications such as in angioplasty procedures (col. 11-18). As shown in figures 2 Barry discloses a catheter (element

30) with a distal end that supports an expansible balloon (element 35) with an expandable stent (element 36). The catheter also has a port (element 42) positioned proximal to the balloon, connected to a therapeutic agent source to inject a anti-restenosis agent such as gene therapy agents into the volume (col. 6 line 21-32, col. 60-68, col. 7 line 1-8). What Barry does not explicitly disclose is use of this stent and therapeutic agent in the coronary blood vessel and in the myocardium. Stevens discloses a method of delivery of therapeutic agents to the heart. Steven also discloses a catheter with a delivery port to deliver a therapeutic agent to the myocardium. He discloses that another agent delivery technique besides the delivery port is to inject the agent directly into the myocardium (col. 8 line 21-40). It would be obvious to combine the apparatus of Barry with the method of Stevens to place the apparatus of Barry (of the catheter, stent, and delivery of therapeutic agent) within the coronary blood vessel as the apparatus of Barry can be used in any vessel. Stevens shows that it is well known in the art to, instead of using a delivery port, one can use a needle to inject a therapeutic agent (such as an anti-stenosis agent) into the myocardium. The stent can be placed in the endocardial or peri-adventitial area, which would mean the therapeutic agent will be injected into the myocardium from these areas. Also the needle can be placed anywhere, such as at a site distal to the stent.

7. **Claims 7-9, 17-19, 27-29 and 37-39** are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view of Stevens further in view of Mixson (US 6,090,728). Mixson discloses carrier vehicles for an anti-angiogenic agents comprising micelles and microspheres.

8. **Claims 10, 20, 30 and 40** are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view of Stevens further in view of Rossi (US 6,379,931 B1). Rossi discloses that therapeutic agents for inhibiting stent induced restenosis can be injected with encapsulated liposomes (col. 6 line 63-67).

9. **Claim 41 is** rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens further in view of Kunz (US 5,981,568). Neither Barry nor Stevens explicitly disclose a kit comprising the parts of their method. It would be obvious to put the parts needed to perform a method in a kit as well as instructions to perform the method as this is well known in the art to do. For example, Kunz discloses not only a kit to perform a method, but also discloses in particular a kit for inhibiting restenosis comprising a catheter, a dose of therapeutic agent, and instruction means for directing the kit's use. Since the method of Stevens comprises positioning the catheter into the desired location (capable of being the perivasular space) and delivering the dose to where the catheter is placed, it would be obvious that the instructions would state this.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

11. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE CHENG whose telephone number is (571)272-5596. The examiner can normally be reached on M-F 10:00-6:30.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian L Casler/
Supervisory Patent Examiner, Art Unit 3737

JC